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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,326	04/01/2004	Jerry Henslee	5972.US.D3	9145

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,326	HENSLEE ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 6-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 6-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 05/18/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 6 and 7) in the reply filed on January 3, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, upon reconsideration Group II (claim 8) has been joined with Group I.

2. Claims 6-8 are pending.

Claims 1-5 are cancelled.

Claims 6-8 are examined on the merits.

Priority

3. The Examiner has reviewed the U.S. Applications from which priority is claimed. The limitations of all the breast cancer markers, mammaglobin (SEQ ID NO: 5), BU101 (SEQ ID NO: 6) and BS106 (SEQ ID NO: 8) have only been disclosed in the instant application and U.S Application 09/975,502 (filed October 11, 2001). Accordingly, claims 6-8 are afforded the priority date of October 11, 2001. One claim is afforded one priority date, which represents the date at which all limitations are disclosed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0009738 (filed April 2, 2001/ IDS reference A5 submitted May 18, 2005). US patent application publication #2002/0009738 discloses Applicants' BS106 (SEQ ID NO: 8) and BU101 (SEQ ID NO: 6), which are the same as the publication's sequence 31 and sequence 77, respectively, see SCORE results, rapbm databases, results 2 and 1, respectively. These molecules are breast tumor proteins. These proteins, as well as the mRNA encoding said proteins are detected in diagnostic methods, see abstract.

"Once a sample is enriched or positively selected, cells may be further analysed. For example, the cells may be lysed and RNA isolated. RNA may then be subjected to RT-PCR analysis using breast tumor-specific multiplex primers in a Real-time PCR assay as described herein.", see page 10, section 0154. "Typically, RNA is extracted from a biological sample, such as blood, serum, lymph node, bone marrow, sputum, urine and tumor biopsy samples, and is reverse transcribed to produce cDNA molecules. PCR amplification using at least one specific primer generates a cDNA molecule, which may be separated and visualized using, for example, gel electrophoresis.", see page 11, sections 0164-0167.

Translation products or the proteins encoded by the disclosed nucleic acids can be detected with a monoclonal antibody or fragment that specifically bind to the breast tumor proteins, see abstract; page 12, section 0179; page 13, section 0181.

6. Claims 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication 2002/0082216 (filed January 8, 2001). US patent application publication #2002/0082216 discloses Applicants' mammaglobin (SEQ ID NO: 5), which is the same as the publication's sequence 27, see SCORE results, rapbm database, result 1; Figure 2; page 2, section 0027; and page 26. This molecule is the human mammaglobin amino acid sequence. The publication discloses "...methods for detecting of RNA encoding mammaglobin..." and consequent detection of breast cancer, see abstract.

"Polynucleotides may be prepared using any of a variety of techniques...Such polynucleotides may be amplified via polymerase chain reaction (PCR).", see page 4, section 0051. "One preferred assay employs RT-PCR, in which PCR is applied in conjunction with reverse transcription. Typically, RNA is extracted from a sample tissue and is reverse transcribed to produce cDNA molecules. PCR amplification using at least one specific primer generates a cDNA molecule, which may be separated and visualized using, for example, gel electrophoresis. Amplification may be performed on samples obtained from biological samples taken from a test patient and an individual who is not afflicted with a cancer.", see page 14, section 0144.

Translation products or the proteins encoded by the disclosed nucleic acids can be detected, with a monoclonal antibody or fragment that specifically bind to the breast tumor proteins, see abstract; page 4, section 0049; page 5, section 0071; and page 14, section 0136.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
28 March 2007